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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Dawn M. Alviar, Plaintiff, v. Boehringer Ingelheim Pharmaceuticals, Inc., GlaxoSmithKline plc, GlaxoSmithKline LLC, Chattem, Inc., Sanofi-Aventis U.S. LLC, and Sanofi US Services Inc. Defendants.	Civil Action No. **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Dawn M. Alviar, in her action against Defendants Boehringer Ingelheim Pharmaceuticals, Inc., GlaxoSmithKline plc, and GlaxoSmithKline LLC (collectively "Glaxo"), Chattem, Inc., Sanofi-Aventis U.S. LLC, and Sanofi US Services Inc. (collectively "Sanofi" or

"Sanofi Defendants") alleges the following based on personal knowledge, the investigation of counsel, and information and belief.

I. INTRODUCTION

1. Recently, the public has been deluged by reports of serious impurities in pharmaceutical drugs. In 2019 alone, there have been dozens of recalls of blood pressure medications such as valsartan (and other angiotensin receptor blockers or "ARB") that contained dangerous levels of a potent carcinogen called *N*-Nitrosodimethylamine or NDMA. In the case of valsartan, the NDMA impurities resulted from shoddy manufacturing practices. This case also involves NDMA associated with a common drug. But unlike the NDMA present in valsartan, the NDMA associated with this common drug is *not* an impurity caused by faulty manufacturing processes. Rather, the NDMA is inherent to the drug itself.

2. This case involves perhaps one of the most sinister and gravest public-health frauds in modern times. Since its launch in 1983, every manufacturer of prescription and over-the-counter Zantac has aggressively pushed a poisonous pill into the stream of commerce, while knowing that, when ingested, *every single tablet* (or every single dose) of Zantac, produces levels of NDMA in amounts that exceed the U.S. Food and Drug Administration's permissible daily limits for the carcinogen by *thousands* of times.

3. As if the formation of NDMA in the body from Zantac use isn't bad enough, once it is present in the body, NDMA further metabolizes into other known carcinogens such as formaldehyde. In short, Zantac is nothing more than a cancerous poison that at all times was sold by Defendants with the actual or constructive knowledge that it was a poison. As a proximate result of Defendants' callous conduct, Plaintiff has Uterine Cancer. This case seeks compensation for Plaintiff's injuries, which were proximately caused by Defendants' egregious actions.

4. NDMA and its metabolites damage DNA through a variety of mechanisms. NDMA or its metabolites can induce alkylating damage. NDMA can literally break the phosphodiester backbone of the double helix (*i.e.*, a "strand break"), directly induce mutations in the DNA sequence, it can chemically modify the DNA molecule, forming "DNA adducts," and split chromosomes.

5. Zantac—the brand-name version of the generic drug ranitidine—is used to treat gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease.[1] Zantac was developed by Glaxo, and first sold in the United States in 1983 in prescription form; three years later, it became the first drug to total $1 billion in sales.[2]

6. As recently as 2018, Zantac was widely used and remained one of the most popular tablet brands of antacid[3] in the United States. Currently, Zantac comes in several formulations. A 300 mg dose that is available by prescription, and 150 mg (Zantac 150) and 75 mg (Zantac 75) doses that are available over-the-counter.

7. But Zantac's unprecedented sales were possible only because of a deception perpetrated by all Zantac manufacturers since the drug hit the U.S. market in 1983.

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[1] *Ranitidine hydrochloride – Drug Summary*, PRESCRIBER'S DIGITAL REFERENCE (last visited Sept. 19, 2019), https://www.pdr.net/drug-summary/Zantac-150-and-300-Tablets-ranitidine-hydrochloride-241.3325.

[2] Richard Wright, M.D., *How Zantac Became the Best-Selling Drug in History*, 16(4) J. HEALTHCARE MARKETING 24 (Winter 1996).

[3] Zantac is not technically an antacid because it "works by reducing the amount of acid [the] stomach makes," whereas antacids "neutralize the acid that your stomach has already made." *See Ranitidine, Oral Tablet*, HEALTHLINE (last visited Sept. 13, 2019), https://www.healthline.com/health/ranitidine-oral-tablet. Nonetheless, this complaint sometimes refers to Zantac as an antacid because this is often how the drug is referred to colloquially. *See, e.g., Leading antacid tablet brands in the United States in 2018, based on sales*, STATISTA (last visited Sept. 13, 2019), https://www.statista.com/statistics/194544/leading-us-antacid-tablet-brands-in-2013-based-on-sales/.

8. From Zantac's commercial launch in 1983 until recently, Glaxo has sold prescription formulations of Zantac. The Sanofi Defendants have owned the U.S. rights to over-the-counter Zantac since about January 2017 and has manufactured and distributed the drug from then until the present. Previously, Defendant Boehringer owned the U.S. rights to over-the-counter Zantac and manufactured and distributed the drug from about October 2006 to January 2017. Before that, Pfizer (and one of its subsidiaries) manufactured and sold over-the-counter Zantac from the time it first went over-the-counter in 1996 through approximately 2005.

9. Each Defendant knew, or should have known, at all times that it sold Zantac, that the drug has a critical and deleterious defect: When ingested, Zantac produces in the human body high quantities of NDMA, a chemical that the World Health Organization has described as "clearly carcinogenic."[4] The dangers of NDMA have been publicly known for over 40 years, well before Zantac hit the market.[5] NDMA itself belongs to a family of chemicals called *N*-nitrosamines, which the U.S. Environmental Protection Agency refers to as "potent carcinogens."[6] The dangers posed by NDMA are bad enough, but once Zantac introduces NDMA into the body, the NDMA breaks down into other harmful substances, such as formaldehyde—a known human carcinogen that has been linked to leukemia and other cancers.

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[4] R.G. Liteplo, et al., *Concise International Chemical Assessment Document 38: N-Nitrosodimethylamine*, WORLD HEALTH ORGANIZATION (2002), *available at* https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

[5] *See, e.g.*, Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979) ("As one of a family of carcinogens called nitrosamines, NDMA has caused cancer in nearly every laboratory animal tested so far.").

[6] https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf (last visited Oct. 17, 2019).

10. That Zantac forms NDMA was most recently confirmed in a series of scientific tests conducted by Valisure LLC and ValisureRX LLC (collectively "Valisure"). In those tests, Valisure "detected extremely high levels of NDMA in *all lots* [*of ranitidine*] *tested,* across multiple manufacturers of ranitidine products," including Zantac.[7]

11. Valisure notified the FDA of its findings by filing a Citizen Petition on September 13, 2019.[8] In addition, Valisure submitted a copy of the Citizen Petition to the World Health Organization and the International Agency for the Research of Cancer to be included in the *IARC Monographs on the Valuation of Carcinogenic Risks to Humans* and to have ranitidine classified as a human carcinogen.[9]

12. Valisure is an "online pharmacy currently licensed in 38 states and an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization."[10] Valisure also is registered with the Drug Enforcement Administration and the FDA.[11] The tests conducted by Valisure show that "ranitidine can react with itself in standard analysis

[7] Valisure Citizen Petition to FDA ("Citizen Petition") at 6 (emphasis added), *available at* https://www.valisure.com/blog/uncategorized/detection-of-ndma-in-raniditine/ (last visited Oct. 24, 2019).

[8] *Id.*

[9] *Id.* The IARC Monographs, "identify environmental factors that are carcinogenic hazards to humans. These include chemicals, complex mixtures, occupational exposures, physical agents, biological agents, and lifestyle factors. National health agencies can use this information as scientific support for their actions to prevent exposure to potential carcinogens." *See* https://monographs.iarc.fr/home/iarc-monographs-general-information/ (last visited Oct. 13, 2019).

[10] Citizen Petition at 2.

[11] *Id.*

conditions . . . at high efficiency to produce NDMA at dangerous levels well in excess of the permissible daily intake limit for this probable carcinogen."[12]

13. The FDA recently announced a permissible intake limit of **96 ng** of NDMA per day.[13] But even this limit may be too high: A public health statement issued 30 years ago by the Agency for Toxic Substances and Disease Registry warned of the dangers posed by NDMA, noting among other things that "high level short-term and *low level long-term exposures* [to NDMA] caused non-cancerous liver damage and/or cancer in animals [and] also usually resulted in internal bleeding and death."[14]

14. Valisure's testing—which employs the FDA's gas chromatography/mass spectrometry ("GC/MS") protocol—detects **2,511,469 ng** of NDMA per a single 150 mg tablet of Zantac.[15] In other words, the FDA protocol detects a quantity of NDMA in each Zantac tablet that is more than **26,000 times** greater than the FDA's daily permissible NDMA intake levels.

15. "The typical recommended dose of ranitidine for therapy of peptic ulcer disease in adults is 150 mg twice daily or 300 mg once nightly for 4 to 8 weeks, and maintenance doses of

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[12] *Id.*

[13] *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)*, FDA (last updated Aug. 28, 2019) (setting "interim limits for NDMA" and other nitrosamines at 96 ng/day for angiotensin II receptor blockers).

[14] Agency for Toxic Substances & Disease Registry, *Public Health Statement for n-Nitrosodimethylamine* 2 (Dec. 1989) (emphasis added), available at https://www.atsdr.cdc.gov/ToxProfiles/tp141-c1-b.pdf. The public health statement also notes that "[s]hort-term or long-term exposure of animals to water or food containing NDMA is also associated with serious effects, such as liver disease and death, at levels ranging from 5 to 50 ppm [parts per million] in water and 5 to 100 ppm in food." *Id.* at 3.

[15] Citizen Petition, *supra* footnote 7, at 6. Some generic versions of ranitidine demonstrated even higher amounts of NDMA. For example, the CVS version of Zantac contained NDMA levels of 3,267,968 ng of NDMA. *Id.*

150 mg once daily."[16] Moreover, chronic use of the drug is common "for therapy of heartburn and indigestion."[17]

16. Thus, a typical user who is taking Zantac over eight weeks to treat peptic ulcer disease is exposed to more than 280,000,000 ng (or 0.28 grams) of NDMA based on the levels of NDMA detected through the FDA's GC/MS test. And a consumer who takes a 150 mg maintenance dose of Zantac once daily is exposed to 889,000,000 ng (0.889 grams) of NDMA annually. Again, the FDA's permissible intake limit of NDMA is 96 ng per day, which translates to just 0.000034 grams per year for consumers who take a daily 150 mg maintenance dose.

17. Zantac is used not only by adults but is also given to children and teenagers to treat gastroesophageal reflux disease, among other things.[18] Further, Zantac is often used by pregnant women to treat pregnancy-related heartburn symptoms; thus, not only is the pregnant woman exposed to NDMA, but her fetus is also exposed to this DNA-damaging compound.

18. In addition to the FDA-recommended testing described above, when Valisure tested Zantac "in conditions simulating the human stomach," the quantity of NDMA detected was as high as 304,500 ng per tablet—**3,171 times** more than the amount that can be safely ingested

[16] *Drug Record: Ranitidine*, NATIONAL INSTITUTES OF HEALTH (updated July 1, 2019), https://livertox.nih.gov/Ranitidine.htm.

[17] *Id.*

[18] *Treatment for GER & GERD in Children & Teens*, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (Apr. 2015), https://www.niddk.nih.gov/health-information/digestive-diseases/acid-reflux-ger-gerd-children-teens/treatment.

daily.[19] This is consistent with recent peer-reviewed scientific literature, which has demonstrated the existence of dangerous levels of NDMA in the urine of those who have taken ranitidine.[20]

19. In addition to testing Zantac for NDMA, Valisure also tested several other alternative drugs to Zantac, to determine if these drugs also contained NDMA. The drugs tested included Pepcid, Prilosec, Nexium, Prevacid, Protonix, AcipHex, and Dexilant. Valisure did not detect any NDMA in any of these drugs.[21]

20. When the news broke on September 13, 2019, that Zantac exposed users to NDMA, "[g]lobal health regulators sounded a coordinated alarm."[22] As further described herein, most countries have pulled Zantac and generic ranitidine from the market. In the U.S., many pharmacies and ranitidine manufacturers themselves (including Glaxo and the Sanofi Defendants) have pulled Zantac from their shelves or have recalled their products.

21. Unfortunately, thus far, the FDA has done very little to protect the American public with respect to Zantac, and its messaging has been contradictory, confusing, and slow. Valisure first notified the FDA in June 2019 about the possibility that NDMA forms from ranitidine; the FDA did nothing, or at least made no public comments about the issue.[23] On September 13, 2019, the FDA issued its first statement acknowledging that Zantac contains

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[19] Citizen Petition, *supra* footnote 7, at 6–7.

[20] Teng Zeng & William A. Mitch, *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 37(6) CARCINOGENESIS 625 (Mar. 18, 2016).

[21] Citizen Petition, *supra* footnote 7, at 15–16.

[22] Anna Edney & John Lauerman, *Carcinogen in Zantac and its generics triggers probes by FDA, EU*, THE HAMILTON SPECTATOR (Sept. 13, 2019), https://www.thespec.com/news-story/9595764-carcinogen-in-zantac-and-its-generics-triggers-probes-by-fda-eu/.

[23] https://www.valisure.com/blog/uncategorized/detection-of-ndma-in-raniditine/ (last visited Oct. 25, 2019).

NDMA but, in a seeming attempt to downplay the issue, claimed that the amount of NDMA detected was low: "The U.S. Food and Drug Administration has learned that some ranitidine medicines, including some products commonly known as the brand-name drug Zantac, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels."[24] Further, although numerous regulators outside of the United States have cautioned those taking Zantac to consider taking an alternative medication given the availability of many safe alternative medicines, the FDA informed the American public that it need not discontinue taking OTC Zantac.[25]

22. But then, seemingly in an about-face, on October 2, 2019, although it provided little detail, the FDA itself acknowledged that it found "unacceptable levels of NDMA in samples of ranitidine."[26] The FDA, however, never disclosed what those levels were, what tests it used, or any other information to help educate the public about its findings.

23. Finally, however, it seems that the FDA is beginning to understand what this complaint lays bare: that when ingested, Zantac forms excessive amounts of cancer-causing compounds in the body. On October 24, an FDA spokesman stated that the FDA is currently "working to understand what happens to NDMA levels in the body, after ranitidine has been exposed to acid in the stomach."[27]

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[24] FDA, *Statement alerting patients and health care professionals of NDMA found in samples of Ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[25] *FDA to review ranitidine after detecting cancer-causing contamination*, PHARMACEUTICAL TECHNOLOGY (Sept. 16, 2019), https://www.pharmaceutical-technology.com/news/fda-ranitidine-review/.

[26] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (last visited Oct. 13, 2019).

[27] https://www.reuters.com/article/us-fda-heartburn-zantac/fda-investigating-whether-zantac-causes-carcinogens-to-form-in-users-idUSKBN1X32NA (last visited Oct. 25, 2019).

24. All Defendants knew, or had reason to know, that Zantac exposes users to unsafe levels of the carcinogen NDMA: During the period that Defendants manufactured and distributed Zantac, numerous scientific studies were published showing, among other things, that ranitidine (the generic bioequivalent of Zantac) forms NDMA when placed in drinking water[28] and that a person who consumes ranitidine has a 400-fold increase of NDMA concentration in their urine.[29]

25. Despite the weight of scientific evidence showing that Zantac exposed users to unsafe levels of the carcinogen NDMA, no Defendant ever disclosed this risk to the FDA, on the drug's label, or through any other means. Had Defendants disclosed that Zantac results in unsafe levels of NDMA in the human body, no person, let alone a reasonable person, would have consumed Zantac (or its generic equivalent). Instead, Defendants put profits over safety and aggressively pushed a dangerous drug into the marketplace, exposing millions of people to cancer.

26. Defendants' conduct has proximately caused the Plaintiff's injuries.

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[28] *See, e.g.*, Massimiliano Sgroi, et al., *N-Nitrosodimethylamine (NDMA) and its precursors in water and wastewater: A review of formation and removal*, 191 CHEMOSPHERE 685 (Oct. 15, 2017); Yong Dong Liu, et al., *Formation Mechanism of NDMA from Ranitidine, Trimethylamine, and Other Tertiary Amines during Chloramination: A Computational Study*, 48 ENVTL. SCI. & TECHNOLOGY 8653 (June 26, 2014); Julien Le Roux, et al., *Chloramination of nitrogenous contaminants (pharmaceuticals and pesticides): NDMA and halogenated DBPs formation*, 45 WATER RESEARCH 3164 (Mar. 26, 2011); Ruqiao Shen & Susan A. Andrews, *Demonstration of 20 pharmaceuticals and personal care products (PPCPs) as nitrosamine precursors during chloramine disinfection*, 45 WATER RESEARCH 944 (Oct. 13, 2010); Giovanni Brambilla & Antonietta Martelli, *Update on genotoxicity and carcinogenicity testing of 472 marketed pharmaceuticals*, 681 MUTATION RESEARCH 209 (Sept. 19, 2008); Giovanni Brambilla & Antonietta Martelli, *Genotoxic and carcinogenic risk to humans of drug–nitrite interaction products*, 635 MUTATION RESEARCH 17 (Dec. 6, 2006).

[29] Zeng & Mitch, *supra* footnote 20.

II. PARTIES

A. Plaintiff

27. Plaintiff Dawn M. Alviar is a resident of Grant, Michigan. Plaintiff Alviar began purchasing and ingesting Zantac in or about 2003. From then on, Plaintiff Alviar ingested at least 2 tablets of Zantac 150 and/or Zantac 150 Acid Reducer and/or Zantac (Ranitidine Tablets and Capsules) per day. As a direct and proximate result of ingesting Zantac, Plaintiff contracted Uterine Cancer. Had Plaintiff been informed that taking Zantac would expose her to unsafe quantities of NDMA such that it could and did cause her to contract Uterine Cancer, she never would have purchased or ingested Zantac. Plaintiff required and incurred and will continue to require and incur expenses in connection with medical treatment as a result of these injuries, which were caused by Defendants' ranitidine-based Zantac products, and their unlawful conduct with respect to Zantac's design, manufacture, marketing, and sale. Plaintiff has endured and will continue to endure pain, suffering, mental anguish, and loss of enjoyment of life as a result of her injuries, has suffered lost earnings and/or a loss of earning capacity, and other injuries and damages to be proven at trial.

B. Defendants

1. Sanofi Defendants

28. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly-owned subsidiary of the French company Sanofi.

29. Defendant Sanofi US Services Inc. is a Delaware corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly-owned subsidiary of the French company Sanofi.

30. Defendant Chattem, Inc. is a Tennessee corporation with a principal place of business at 1715 West 38th Street Chattanooga, Tennessee 37409, and is a wholly-owned subsidiary of the French company Sanofi. Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants") controlled the U.S. rights to over-the-counter Zantac from about January 2017 to the present and manufactured and distributed the drug in the United States during that period.

2. Boehringer

31. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") is a Delaware corporation with a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877, and is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer owned the U.S. rights to over-the-counter Zantac from about October 2006 to January 2017, and manufactured and distributed the drug in the United States during that period.

3. Glaxo Defendants

32. Defendant GlaxoSmithKline plc, is an English corporation with its principal place of business at 980 Great West Road, Brentford, Middlesex, England. Defendant GlaxoSmithKline plc is the successor-in-interest to the companies that initially developed, patented, and commercialized the molecule known as ranitidine. Ranitidine was initially developed by Allen & Hanburys Ltd. Allen & Hanburys was acquired by Glaxo Labs Ltd. in 1958,[30] and thus, at the time ranitidine was discovered in the late 1970s, Allen & Hanburys was a subsidiary of Glaxo. Allen &

[30] *See, e.g.*, p. 330, "Glaxo: A History to 1962." R. P. T. Davenport-Hines, Judy Slinn, Cambridge University Press, Nov 26, 1992.

Hanburys Ltd. was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule. GlaxoSmithKline plc also conducted the clinical and other trials associated with Glaxo's New Drug Application (NDA 18703) submitted to the FDA for Zantac. In 1983, Glaxo Holdings, Ltd. was awarded approval by the U.S. FDA to sell Zantac in the United States.

33. Defendant GlaxoSmithKline LLC is a Delaware limited liability corporation with its principal place of business in Philadelphia, Pennsylvania. Since 1983, GlaxoSmithKline LLC, either directly, or through a subsidiary, marketed prescription forms of Zantac in the United States.

34. Defendants GlaxoSmithKline plc and GlaxoSmithKline LLC (collectively "Glaxo"), from 1983 through 1996, had exclusivity with respect to Zantac and were the sole manufacturer and seller of prescription forms of Zantac. Following 1996, Glaxo also sold over-the-counter versions of Zantac and continued to sell the prescription version of Zantac until recently.

III. JURISDICTION AND VENUE

35. Jurisdiction exists under 28 U.S.C. § 1332(a), as well as under 28 U.S.C. § 1367(a), because Plaintiff and Defendants are citizens of different states and the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs.

36. The Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in this District. Defendants' unlawful conduct has injured persons residing in, located in, or doing business throughout this District.

37. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), in that each Defendant transacts business in, is found in, and/or has agents in this district, and because a substantial part of the events giving rise to this action occurred within this district.

IV. FACTUAL ALLEGATIONS

A. A History of Zantac

1. Glaxo has known of the dangers of ranitidine both before and after Zantac's commercial launch in 1981.

38. Zantac/ranitidine belongs to a class of medications called histamine H_2-receptor antagonists (or H_2 blockers), which decrease the amount of acid produced by the stomach and are used to treat gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.[31] Ranitidine was discovered by John Bradshaw in 1976.[32] Mr. Bradshaw, who is deceased, discovered ranitidine while working as a chemist for Allen and Hanburys, which was acquired by Glaxo in 1958. Glaxo specifically developed ranitidine in response to the then leading H_2 blocker, cimetidine (Tagamet).[33] At the time of its discovery and launch, Glaxo touted the safety and effectiveness of ranitidine over competing drugs like cimetidine.[34]

39. Bradshaw, and her co-inventors, Barry J. Price, and John W. Clitherow, also of Allen & Hanburys Ltd. in London, England, applied for a patent with U.S. Patent and Trademark Office on July 25, 1977, to patent ranitidine. The patent was granted on December 5, 1978, and Allen & Hanburys was issued patent No. 4,128,658 by the U.S. PTO.

40. At the time that ranitidine was developed, there was already existing scientific literature strongly suggesting that drugs like ranitidine, which contain a dimethylamine (*DMA*)

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[31] *Histamine H2 Antagonist (Oral Route, Injection Route, Intravenous Route)*, MAYO CLINIC (last updated Aug. 1, 2019), https://www.mayoclinic.org/drugs-supplements/histamine-h2-antagonist-oral-route-injection-route-intravenous-route/description/drg-20068584.

[32] https://blogs.sciencemag.org/pipeline/archives/2011/11/18/two_from_glaxos_old_days (Last visited Oct. 14 2019).

[33] https://wikilawinfo.blogspot.com/2018/06/ranitidine.html (last visited Oct. 14, 2019).

[34] *Id.*

group, are highly likely to form NDMA, when combined with other substances like, for example, nitrite found in the body. The dangers of NDMA formation from ranitidine should have been obvious to Glaxo. For example, one taking Zantac would likely be doing so in connection with a meal. Many meals contain additional nitrates above that which is found naturally in the body. Bacteria found within the saliva and stomach, or enzymes in the body, can *reduce* the nitrates (NO_3) found in food into nitrites (NO_2^-). Additionally, some nitrites are found naturally in food or added as a preservative. Thus, at the time of ranitidine's discovery, Glaxo scientists should have known that the very events that would lead one to take Zantac, also put such person at risk of NDMA formation from Zantac due to increased nitrite levels in the body reacting with the ranitidine or its constituents.

41. Further, in 1981, the very year Zantac was launched commercially outside of the US, two exchanges in *The Lancet*, one of which involving Glaxo, discussed the potential toxicity of cimetidine and ranitidine. Cimetidine, also an H_2 blocker, has a similar chemical structure to ranitidine. *The Lancet* was and is one of the most widely read and respected medical and scientific publications, and thus, Glaxo (and the other Defendants) would have been aware of material related to ranitidine.

42. In one exchange, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, wrote into *The Lancet* describing how the researchers detected "mutagenic nitroso derivatives" *in vitro* for both cimetidine as well as ranitidine.[35] De Flora did recognize that her studies were *in vitro*, and that, as such, they weren't perfectly predictive of how ranitidine would

[35] S. De Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, THE LANCET at pp. 993-994 (Oct. 31, 1981)

perform in humans. Glaxo was aware of this article because it specifically responded to it in *The Lancet* and sought to try and discredit de Flora's research. In its response, Glaxo cited to a study it had recently performed on ranitidine itself, which appears to have been flawed. Notwithstanding that the study was likely flawed, Glaxo nonetheless admitted to detecting a "product" that was "mutagenic" in ranitidine, although it failed to clearly specify what that "product" was.[36]

43. In a second set of articles in *The Lancet* around the same time as the de Flora article, medical researchers from England discussed a study they performed on 140 human patients taking cimetidine. Their study observed that those who took cimetidine had a much higher level of *N*-nitrosamines than those in a control group who didn't take cimetidine.[37] In response, Roger Brimblecombe, a researcher from Smith Kline and French Research, Ltd.,[38] criticized the research performed by Reed and referenced unnamed "extensive studies" purportedly claiming that they demonstrate no "aetiological link between cimetidine treatment and the development of gastric cancer."[39] Importantly, Brimblecombe also stated that, "[t]he hypotheses raised by Reed and her colleagues are important and have been publicly and extensively discussed over the past two and

[36] R.T. Brittain, D.M. Harris, L.E. Martin, D. Poynter, B.J. Price, *The Safety of Ranitidine*, THE LANCET, p. 1119 (Nov. 14, 1981). The article notes that these researchers are from "Glaxo Group Research Ltd." in England.

[37] P. I. Reed, K. Haines, P.L.R. Smith, F.R. House, C.L. Walters, *Effect of Cimetidine on Gastric Juice N-Nitrosamine Concentration*, THE LANCET (Sept. 12, 1981).

[38] Smith Kline and French was part of the Smith Kline Beecham group, which merged with Glaxo in or around 2000. https://www.gsk.com/media/4573/300yrs-of-gsk.pdf (last visited Oct. 18, 2019). Smith Kline and French was the innovator and manufacturer of cimetidine (Tagamet). https://www.acs.org/content/acs/en/education/whatischemistry/landmarks/cimetidinetagamet.html (last visited Oct. 21, 2019).

[39] Roger Brimblecombe, *Cimetidine, Nitrosation, and Carcinogenicity*, THE LANCET at pp. 686-687 (Sep. 26, 1981)

half years. A great deal of research, both in our laboratories and in others, is in progress."[40] This clearly demonstrates that the formation of nitrosamines related to cimetidine and ranitidine, was one that was known to Glaxo and others, as it was a subject of much discussion in the scientific community at this time.

44. On December 5, 1981, Dr. Reed then responded to Brimblecombe, noting that, among other things, the studies Brimblecombe relied upon have been harshly criticized by others.[41] Reed also noted, "[d]ebate on N-nitroso compounds and human gastric cancer continues but some involvement seems likely . . . . If N-nitrosamine concentrations are raised in certain conditions with an increased risk of gastric cancer then this is a hint which must not be ignored."[42] Dr. Reed and his co-authors sounded the alarm on Zantac, but no one, including Glaxo, listened.

45. In 1983, a further study was published, this time specifically relating to ranitidine. Dr. Silvio de Flora (the same scientist who authored the 1981 piece in *The Lancet* that Glaxo sought to discredit) and a group of researchers from the University of Genoa in Italy published a study specifically describing the formation of *N*-nitrosamines from ranitidine and an excess of nitrite under certain conditions.[43] On information and belief, Glaxo, and the other Defendants, were aware of this study.

46. Further, also in 1983, yet another article was published specifically implicating the toxicity of ranitidine. Another group of Italian researchers from the University of Genoa

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[40] *Id.*

[41] P. I. Reed, K. Haines, C.L. Walters, S.L.R. Smith, and F.R. House, *Cimetidine, Nitrosation, and Carcinogenicity*, THE LANCET at pp. 1281-1282 (Dec. 5, 1981).

[42] *Id.*

[43] Silvio De Flora, Carlo Bennicelli, Anna Camoirano, and Patrizia Zanacchi, *Genotoxicity of nitrosated ranitidine*, CARCINOGENESIS, Vol. 4, No. 3, pp. 255-260 (1983).

discovered that *in vitro*, and under certain conditions, ranitidine had the tendency to form DNA-damaging nitroso compounds (like NDMA). Although the study was done on hamsters, and utilized conditions not necessarily identical to those that would be found in the human body, the study called for more research to be done into what conditions nitroso compounds formed as a result of ranitidine ingestion.[44] On information and belief, Glaxo, and the other Defendants, were aware of this study.

47. Further evidence of Glaxo's knowledge that Zantac formed NDMA in the body comes from a human study it was involved in and that was published in 1987.[45] In that study, the researchers tracked 15 patients who took ranitidine and had their gastric juice examined following ingestion of Zantac. Critically, instead of using the gold standard assay at the time (and which remains the case today) — mass spectrometry — to detect for the presence of nitrosamines in the human subjects, Glaxo used a nitrogen-oxide (i.e., nitric oxide, NO) assay which essentially was designed not to find nitrosamines.

48. Although the assay allegedly can detect *N*-nitrosamines, the sensitivity of the assay to detect NDMA is not established within the peer-reviewed literature. When the study team tested gastric fluid samples containing ranitidine, the nitrogen oxide assay indicated the presence of *N*-nitroso compounds (*e.g.*, NDMA).[46] However, rather than exploring this further, the authors

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[44] Annalisa Maura, Albiana Pino, Luigi Robbiano, Enrica Cajelli, Renata Finollo, Marco Cavanna and Giovanni Brambilla, DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells, TOXICOLOGY LETTERS, 18, 97-102 (1983).

[45] *See* J Meyrick Thomas, JJ Misiewicz, AR Cook, MJ Hill, PLR Smith, CL Walters, JK Forster, LE Martin, and DF Woodings, *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 28 GUT. At pp. 726-738 (1987).

[46] *Id.* at p. 730.

claimed that these results were "fals[e]" and then restricted all tests to "ranitidine free samples," to avoid high readings of *N*-nitroso compounds.[47] Upon information and belief, these results were *not* false, and in fact, were a warning sign to Glaxo scientists that ranitidine did generate carcinogenic *N*-nitroso compounds like NDMA. Scientists at Valisure have demonstrated that when ranitidine is incubated in simulated gastric fluid with nitrite, high levels of NDMA are formed. However, rather than exploring this issue further, the study team simply did not test any study samples that had ranitidine in them.

49. In fact, on information and belief, Glaxo never used a mass spectrometry assay to test for the presence of nitrosamines in this study, or, in any of the studies and trials it did in connection with its trials associated with its ranitidine NDA. That is because, as explained above, when using GC/MS (which requires heating of up to 130 degrees Celsius), excessive amounts of nitrosamines are formed. And, had Glaxo used a GC/MS assay, which would have necessarily resulted in the formation of large amounts of NDMA, the FDA would never have approved Zantac as being safe.

2. Zantac becomes wildly successful.

50. Zantac was approved for prescription use by the FDA in 1983.[48] Due in large part to Glaxo's marketing strategy, Zantac was a wildly successful drug, reaching $1 billion in total sales in December 1986.[49] As one 1996 article put it, Zantac became "the best-selling drug in history as a result of a shrewd, multifaceted marketing strategy that . . . enabled the product to dominate the

[47] *Id.*

[48] Wright, *supra* footnote 2, at 26.

[49] *See* Wright, *supra* footnote 2, at 27.

acid/peptic marketplace."[50] Critically, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.[51]

51. Zantac became available without a prescription in 1996,[52] and generic versions of the drug (ranitidine) became available the following year.[53] Although sales of brand-name Zantac declined "as a result of generic and alternative products,"[54] Zantac sales have remained strong over time. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million[55]—a 3.1% increase from the previous year.[56]

52. The rights to Zantac in the U.S. have changed hands several times. In 1996, Zantac was first approved by the FDA for over-the-counter sale. At that time, the over-the-counter version was sold by a joint venture between Glaxo and Warner-Lambert, formed to market Zantac and other over-the-counter drugs.[57] That joint venture ended in 1998, with Warner-Lambert (which was acquired by Pfizer) retaining the right to market Zantac.[58] Defendant Boehringer acquired the U.S.

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[50] *See* Wright, *supra* footnote 2, at 25

[51] *See* Wright, *supra* footnote 2, at 27.

[52] Wright, *supra* footnote 2, at 28.

[53] David Ranii, *Generic Zantac on market*, NEWS AND OBSERVER (Aug. 5, 1997).

[54] *GlaxoSmithKline – Product Portfolio*, PHARMACEUTICALS COMPANY ANALYSIS (Jan. 21, 2003) (Lexis Advance).

[55] *Leading antacid tablet brands in the United States in 2018*, *supra* footnote 3.

[56] *Sales growth of leading brands of antacid tablets in the United States in 2018 (change to prior sales year)*, STATISTA (last visited Sept. 13, 2019), https://www.statista.com/statistics/194547/us-sales-growth-of-antacid-tablet-brands-in-2013/.

[57] *Business Briefs: Warner-Lambert Increases OTC Stake*, American Health Line (Dec. 20, 1995) (available through Lexis Advance).

[58] *Warner-Lambert/Glaxo: To End Joint Venture*, American Health Line (Aug. 4, 1998) (available through Lexis Advance).

rights to over-the-counter Zantac in late 2006,[59] and manufactured and sold the drug in the United States from approximately January 2007 to January 2017.[60]

53. The Sanofi Defendants acquired the U.S. rights to over-the-counter Zantac in approximately January 2017 and have since that time been manufacturing and selling the over-the-counter version of the drug in the United States.[61] Since its launch in 1983, Glaxo has and continues to sell the prescription version of Zantac.

3. Throughout the relevant period, and throughout each period of time each Defendant marketed and sold Zantac, the scientific community continued to raise concerns about NDMA formation from ranitidine.

54. As set forth above, even before ranitidine's launch, and shortly after its launch, serious questions were raised about the safety of ranitidine. Specifically, questions were raised as to whether ranitidine ingestion can lead to the formation of highly carcinogenic NDMA within the human body. As time went on, the scientific evidence establishing that NDMA is formed from ranitidine, in the body, and in other conditions, continued to pile up.

55. For example, a 2011 scientific study found that, out of eight pharmaceuticals that were observed, "ranitidine showed the strongest potential to form N nitrosodimethylamine (NDMA)" when present in drinking water during chloramine disinfection.[62] The same study noted

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[59] *Boehringer Ingelheim Pharmaceuticals, Inc. Announces Agreement to Acquire Zantac® from Johnson & Johnson and the Pfizer Consumer Healthcare Business*, BUSINESS WIRE (Oct. 12, 2006).

[60] *See Digesting an acquisition: Patrick Hennig, Boehringer Ingelheim; Ingelheim Pharmaceuticals to acquire U.S. rights for Zantac product line; Interview*, DRUG STORE NEWS (Mar. 5, 2007); Mike Pare, *Chattem adds Zantac, Dulcolax to portfolio*, CHATTANOOGA TIMES FREE PRESS (TENNESSEE) (Feb. 8, 2017).

[61] *Chattem adds Zantac*, *supra* footnote 61.

[62] Ruqiao Shen & Susan A. Andrews, *Demonstration of 20 pharmaceuticals and personal care products (PPCPs) as nitrosamine precursors during chloramine disinfection*, 45 WATER RESEARCH 944 (Oct. 13, 2010). "Chloramination is the process of adding chloramine to drinking water to

that "[r]anitidine gave a much higher yield of NDMA in the present study than reported in [prior] literature."[63] On information and belief, the Defendants were aware of this study. Another 2011 scientific article that examined ranitidine in the water supply also found that the drug was "an important NDMA precursor."[64] On information and belief, the Defendants were aware of this study.

56. A 2014 scientific article that examined the formation mechanisms of NDMA acknowledged the consensus about the dangers posed by ranitidine, observing that ranitidine and two other pharmaceuticals had "recently caused much concern because they are potent NDMA precursors."[65] On information and belief, the Defendants were aware of this study.

57. A peer-reviewed study published in the scientific journal *Carcinogenesis* in 2016 "confirmed the production of *N*-nitrosodimethylamine (NDMA), a potent carcinogen, by nitrosation of ranitidine under stomach-relevant pH conditions in vitro" and also showed that, during the 24 hours following ranitidine intake, the quantity of NDMA in urine excreted by the patient "increased 400 folds from 110 to 47 600 ng."[66] The article noted that these levels of NDMA "equaled or exceeded those observed previously in patients with schistosomiasis, a disease wherein

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disinfect it and kill germs. Chloramination is sometimes used as an alternative to chlorination." *Disinfection with Chloramine*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Jan. 20, 2015), https://www.cdc.gov/healthywater/drinking/public/chloramine-disinfection.html.

[63] *Id.* at 948.

[64] Julien Le Roux, et al., *Chloramination of nitrogenous contaminants (pharmaceuticals and pesticides): NDMA and halogenated DBPs formation*, 45 WATER RESEARCH 3164 (Mar. 26, 2011).

[65] Yong Dong Liu, et al., *Formation Mechanism of NDMA from Ranitidine, Trimethylamine, and Other Tertiary Amines during Chloramination: A Computational Study*, 48 ENVTL. SCI. & TECHNOLOGY 8653 (June 26, 2014).

[66] Teng Zeng & William A. Mitch, *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 37(6) CARCINOGENESIS 625 (Mar. 18, 2016).

N nitrosamines are implicated as the etiological agents for bladder cancer."[67] The article also cautioned that these "estimates are conservative": The actual exposure to NDMA is "likely much higher than that eliminated in urine" since NDMA has "a high metabolic conversion rate" so that only about 0.05% of NDMA in the body is excreted in urine.[68] The authors of the study concluded that "a more comprehensive risk assessment"—such as "[e]pidemiological studies evaluating cancer risk, particularly bladder cancer, attributable to the long term use of ranitidine"— was needed because of "the widespread use of ranitidine."[69] The authors also noted that "alternative medications, such as proton pump inhibitors (PPIs), would less likely promote in vivo nitrosation because of the lack of amines in their structure."[70] On information and belief, the Defendants were aware of this study.

58. A 2018 scientific review "summariz[ing] major findings over the last decade related to N Nitrosodimethylamine (NDMA)" again pointed out that ranitidine had a high rate of NDMA formation "upon chloramination." On information and belief, the Defendants were aware of this study.

59. Not only was there a significant amount of scientific literature that continued to pile up establishing NDMA formation from ranitidine, but studies were also published specifically linking Zantac to certain types of cancers in humans. For example, in 2004 an extensive

[67] *Id.*

[68] *Id.* at 632.

[69] *Id.* at 632-633.

[70] *Id.*

epidemiology study was published specifically linking Zantac use to bladder cancer.[71] In that study, nearly 51,000 health professionals (such as dentists, veterinarians, pharmacists) were studied over nearly 15 years to assess the relationship between peptic ulcer disease and bladder cancer. As part of that study, the study participants' use of H_2 blockers (which included both cimetidine and Zantac), were monitored. The study's authors noted that for those participants who took either cimetidine or Zantac, "[w]e observed an increase in bladder cancer risk among men who reported taking either of these medications . . . ."[72]

60. Despite the undeniable scientific evidence linking ranitidine to the production of high levels of NDMA, or, the mounting evidence that Zantac itself is linked to cancer, Defendants did not disclose this link to consumers on Zantac's label or through any other means. Since Zantac has been commercially available, by prescription and over-the-counter, the FDA has never been presented with any disclosure by any Defendant, concerning the risk of NDMA formation from ranitidine. Surely, if it had, the FDA would never have approved the drug for use.

B. The Dangers of *N*-Nitrosodimethylamine (NDMA)

61. "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes. It is a member of N-nitrosamines, a family of potent carcinogens."[73]

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[71] Dominque S. Michaud, Pauline A. Mysliwiec, Walid Aldoori, Walter C. Willet, and Edward Giovannucci, *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION, Vol. 13 250-254 (Feb. 2004).

[72] *Id.* at 252.

[73] *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)*, ENVIRONMENTAL PROTECTION AGENCY (Jan. 2014), https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_ndma_january2014_final.pdf.

62. The dangers that NDMA poses to human health have long been recognized. A news article published in 1979 noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[74] NDMA is no longer produced or commercially used in the United States, except for research.[75] In other words, it is only a poison.

63. Both the EPA and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen.[76] And the World Health Organization has stated that scientific testing indicates that "NDMA consumption is positively associated with either gastric or colorectal cancer" and "suggests that humans may be especially sensitive to the carcinogenicity of NDMA."[77]

64. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.[78]

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[74] Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger grows as officials unable to trace poison in reserve's water*, THE GLOBE AND MAIL (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); S.A. Kyrtopoulos, *DNA adducts in humans after exposure to methylating agents*, 405 MUTATION RESEARCH 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumours, including tumours of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

[75] *Technical Fact Sheet*, *supra* footnote 74.

[76] *Technical Fact Sheet*, *supra* footnote 74; World Health Organization, *N-Nitrosodimethylamine (NDMA)*, GUIDELINES FOR DRINKING-WATER QUALITY (3rd ed. 2008) [hereinafter *WHO Guidelines*], *available at* https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

[77] *WHO Guidelines*, *supra* footnote 76.

[78] *See, e.g.*, Karen De Witt, *Carcinogen Fear Allayed*, THE NEW YORK TIMES (July 2, 1980) (reporting recall of beer that contained higher level of nitrosamines than that permitted by FDA).

65. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—valsartan, losartan, and irbesartan—because the medications "contain[ed] nitrosamine impurities that don't meet the [FDA's] safety standards,"[79] which provide that the intake of NDMA should be no more than 96 ng.[80] The highest level of NDMA detected by the FDA in any of the valsartan tablets was 20.19 µg (or 20,190 ng) per tablet.[81] In the case of valsartan, the NDMA was an impurity caused by a manufacturing defect, and thus NDMA was present in only *some* valsartan products.

66. Zantac poses a greater safety risk than any of the recently recalled valsartan tablets. Applying the FDA's GC/MS protocols for detecting NDMA—the same protocols used by the FDA to detect NDMA in valsartan[82]—the level of NDMA in Zantac is 2,511,469 ng per Zantac tablet—**124 times** more than the highest amount detected in the recalled valsartan.[83]

67. Moreover, the high levels of NDMA that Zantac produces are not caused by a manufacturing defect but rather are inherent to the molecular structure of ranitidine, the active ingredient in Zantac: "The ranitidine molecule contains both a nitrite and a dimethylamine

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[79] *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, FDA (May 23, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan.

[80] *FDA Updates and Press Announcements*, *supra* footnote 13.

[81] *See Laboratory analysis of valsartan products*, FDA (May 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products.

[82] *Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay by GC/MS-Headspace*, FOOD & DRUG ADMINISTRATION (Jan. 25, 2019), https://www.fda.gov/media/117843/download.

[83] *See* Citizen Petition, *supra* footnote 7, at 5; *Combined N-Nitrosodimethylamine*, *supra* footnote 82.

('DMA') group which are well known to combine to form NDMA."[84] Thus, ranitidine produces NDMA by "react[ing] with itself,"[85] which means that *every dosage and form of ranitidine*, including Zantac, exposes users to NDMA.[86]

68. NDMA in and of itself is toxic. But, NDMA is not the final harmful metabolite produced from ranitidine. NDMA itself is further metabolized by the body into other harmful compounds. For example, it is well-established that NDMA is metabolized by the body into formaldehyde. Formaldehyde is a *known* carcinogen.[87] IARC classifies something as a known carcinogen when "there is sufficient evidence of carcinogenicity in humans."[88] In addition to IARC's designation of formaldehyde as a known carcinogen, the United States itself has designated formaldehyde as a known carcinogen. In 2014, The National Toxicology Program, a division of the U.S. Department of Health and Human Services, classified formaldehyde as a known human carcinogen.[89] Formaldehyde has been specifically linked to various types of cancers. In 2009, IARC stated that "there is sufficient evidence for a causal association of formaldehyde with leukemia."[90]

69. At all times relevant to this complaint, there was never any debate about the toxicity and lethality of NDMA. However, at one time, long ago, much of the literature linking NDMA to

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[84] Citizen Petition, *supra* footnote 7, at 19.

[85] Citizen Petition, *supra* footnote 7, at 2.

[86] Citizen Petition, *supra* footnote 7, at 1.

[87] https://www.cancer.org/cancer/cancer-causes/formaldehyde.html (last visited Oct. 16, 2019).

[88] https://monographs.iarc.fr/wp-content/uploads/2019/07/Preamble-2019.pdf, at p. 35 (last visited Oct. 14, 2019).

[89] https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet#r3 (last visited Oct. 14, 2019).

[90] https://www.atsdr.cdc.gov/toxprofiles/formaldehyde_addendum.pdf, at p. 47 (last visited Oct. 14, 2019).

cancers, were based on animal studies. And, such studies linked NDMA to carcinogenesis and other adverse health consequences. In one example referenced above, a news article published in 1979 (four years prior to Zantac's launch), noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."

70. However, more recently, there have been several important studies, including extensive epidemiological studies, which found that NDMA is a causal agent in various types of cancers. For example, one epidemiology study that just was published this year, followed over 30,000 individuals for over 40 years, and who were exposed to NDMA. The study found strong linkages between NDMA exposure and cancer in humans. Thus, much like there was never any debate about how toxic NDMA is, there is now no debate as to its causal connection to cancer *in humans*.

71. Further, it is also true that nitrosamines like NDMA are found in certain foods in very low amounts. For example, in the FDA's September 13, 2019 release first announcing that it detected NDMA in ranitidine it tested, it stated, "NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables."[91] However, the levels of NDMA formed in the human body as a result of ranitidine ingestion far exceed the amount of NDMA that could *ever* be found in food making NDMA levels in food an inapt comparison to ranitidine.

72. For example, as set forth above, in 2016, Professors Mitch and Zeng found that in the 24-hour period following ingestion of a single 150 mg tablet of Zantac, an individual can

[91] https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine (last visited Oct. 15, 2019).

excrete nearly 47,000 ng of NDMA. For comparison, the United States Department of Agriculture ("USDA") has found that cooked cured bacon – commonly thought to be a food with a high level of nitrosomines – has, on average of 0.53 ng of NDMA per gram.[92]

73. This means that for an individual to be exposed to the same level of NDMA that Mitch and Zeng measured (*i.e.*, 47,000 ng) following ingestion of *a single* 150 mg ranitidine tablet, they would have to consume more than *178 pounds* of bacon within 24 hours. Of course, such exposure through bacon consumption would be impossible – as other, more acute, health concerns would be experienced by an individual attempting to consume that quantity of food in such a short time.

74. The Mitch and Zeng study, however, as pointed out above, underestimated the level of NDMA exposure experienced by patients in the study — the authors state that only approximately 0.05% (*i.e.*, one two thousandth) of NDMA is excreted through urine, with this being metabolized into other compounds. Thus, in reality, one would have to consume thousands of pounds of bacon to reach the same levels of NDMA found in a *single* Zantac tablet.

75. The NDMA levels associated with Zantac pose an extreme risk to cancer in humans. In the FDA's press releases related to the various angiotensin receptor blocker recalls, the FDA modeled some cancer risks associated with the amount of NDMA found in the ARB medications. For example, the FDA stated, "FDA scientists estimate that if 8,000 people took the highest valsartan dose (320 mg) from the recalled batches daily for the full four years, there may be

[92] *See* https://www.fsis.usda.gov/wps/wcm/connect/25a03ca6-cdce-4e56-bfca-b634cc7abbef/nitrosamine-risk-assessment.pdf?MOD=AJPERES at Table 2.

one additional case of cancer over the lifetimes of these 8,000 people."[93] As stated above, the highest level of NDMA detected with respect to the ARB medicines was 20,190 ng. Given that NDMA levels in urine of those in the Mitch and Zeng Study who took Zantac was 47,000 ng, and that amount likely represents only 0.5% of the amount of NDMA formed in the body from a Zantac tablet, using the FDA's calculations, the cancer risks of those who take Zantac are *well* below 1 in 4000.

C. Defendants did not disclose to Plaintiffs, the FDA or anyone else that Zantac exposes users to high levels of the carcinogen NDMA, despite having actual or constructive knowledge of this fact.

76. During the time that Defendants manufactured and sold over-the-counter Zantac in the United States, the weight of scientific evidence showed that Zantac exposed users to unsafe levels of NDMA. At no time did any Defendant ever disclose this risk to consumers on the drug's label, or through any other means, nor did Defendants report these risks to the FDA. Further, no Defendant presented to the FDA a proposed label disclosing the risks for NDMA formation from ranitidine, and therefore, the FDA never ruled upon any proposed label disclosing the NDMA risk.

D. Most global health regulators, and manufacturers themselves, have recalled their Zantac and ranitidine products.

77. Since the filing of the Valisure's Citizen Petition on September 13, 2019, virtually every health regulator throughout the world, with the exception of the U.S. FDA, has taken steps

[93] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last visited Oct. 16, 2019).

to remove Zantac and ranitidine from the marketplace. In addition, many manufacturers, including Glaxo and the Sanofi Defendants, have also recalled the drug.

78. At the request of Health Canada, the department of the Canadian government responsible for national public health, "companies marketing ranitidine products in Canada have stopped any further distribution until evidence is provided to demonstrate that they do not contain NDMA above acceptable levels."[94] According to Canadian regulators, "[c]urrent evidence suggests that NDMA may be present in ranitidine, regardless of the manufacturer."[95]

79. Similarly, South Korea's Ministry of Food and Drug Safety has stated that "[i]t suspects NDMA may have been unintentionally produced *in the course of natural decomposition and synthesis reactions of the nitrite and dimethylamine chemicals in ranitidine* or by dimethylamine accidentally being added during the manufacturing process."[96]

80. Germany, Switzerland, and Austria all have initiated recalls of ranitidine-based drugs,[97] and Finland has withdrawn drugs containing ranitidine from its pharmacies.[98] Singapore

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[94] *Information Update – Health Canada requests that companies stop distributing ranitidine drugs in Canada while it assesses NDMA; some products being recalled*, CISION CANADA (Sept. 17, 2019), https://www.newswire.ca/news-releases/information-update-health-canada-requests-that-companies-stop-distributing-ranitidine-drugs-in-canada-while-it-assesses-ndma-some-products-being-recalled-821911993.html.

[95] *Id.*

[96] *Korea bans sales of Zantac and other ranitidine drugs after carcinogen alert*, Pulse (Sept. 26, 2019), https://m.pulsenews.co.kr/view.php?year=2019&no=769561.

[97] Tom Gallen, *Ranitidine Recalls Begin In Europe As Regulators Take Action*, PHARMA INTELLIGENCE (Sept. 18, 2019), https://hbw.pharmaintelligence.informa.com/RS149219/Ranitidine-Recalls-Begin-In-Europe-As-Regulators-Take-Action.

[98] *Pharmacies pull heartburn meds over contamination concerns*, UUTISET (Sept. 19, 2019), https://yle.fi/uutiset/osasto/news/pharmacies_pull_heartburn_meds_over_contamination_concerns/10977530.

has suspended the sale and supply of several brands of ranitidine.[99] Qatar's Ministry of Public Health "has withdrawn samples of ranitidine, including the one commercially known as Zantac, from public and private pharmacies" and has "recommend[ed] patients who use these drugs to review and consult their doctor, and those who use them without a prescription should use other alternatives."[100] In addition to these countries, the following countries have either issued recalls, medical alerts, announced an investigation, or companies voluntarily recalled their Zantac and/or generic ranitidine:

- Australia
- Bangladesh
- Bahrain
- Cyprus
- Denmark
- Egypt
- France
- Greece
- Hong Kong
- India
- Ireland
- Jamaica
- Kenya
- Kuwait
- Italy
- Japan
- Libya
- Lithuania
- Morocco
- New Zealand
- Namibia
- Norway
- Oman

[99] *Singapore halts sales of some antacids over stomach cancer concerns*, SOUTH CHINA MORNING POST (Sept. 16, 2019), https://www.scmp.com/news/asia/southeast-asia/article/3027521/singapore-halts-sales-some-antacids-over-stomach-cancer.

[100] *Health ministry recalls Zantac as a precautionary measure*, QATAR TRIBUNE (Sept. 16, 2019), http://www.qatar-tribune.com/news-details/id/172460.

- Palestine
- Pakistan
- Saudi Arabia
- South Africa
- Suriname
- Taiwan
- Trinidad and Tobago
- UAE
- UK
- Vietnam[101]

81. Some companies that manufacture and distribute Zantac and generic ranitidine also have taken action to protect consumers. Most recently, on October 18, 2019, Zantac's current manufacturer, Defendant Sanofi, issued a recall of its Zantac in the U.S. and Canada.[102] In its release announcing the recall, Sanofi stated that "Due to inconsistencies in preliminary test results of the active ingredient used in the U.S. and Canadian products, Sanofi has made the decision to conduct the voluntary recall in the U.S. and Canada as the investigation continues."[103] On October 9, 2019, Glaxo announced that it was pulling its Zantac product from the marketplace worldwide.[104] Sandoz, a unit of Novartis AG, has stopped its "worldwide distribution of generic

[101] https://www.valisure.com/blog/uncategorized/detection-of-ndma-in-raniditine/ (last visited Oct. 25, 2019).

[102] https://www.usatoday.com/story/news/health/2019/10/18/sanofi-recalls-heartburn-drug-zantac-investigate-carcinogen/4021833002/ (last visited Oct. 18, 2019).

[103] *Id.*

[104] https://www.fiercepharma.com/manufacturing/gsk-joins-other-drugmakers-recalling-zantac-products.

versions" of Zantac.[105] And Dr. Reddy's Laboratories Limited has suspended its supply of generic Zantac (ranitidine) worldwide.[106]

82. Other large pharmacies in the U.S. have also pulled Zantac and generic equivalents from their shelves. On September 30, 2019, pharmacy giants CVS, Walgreens, and Rite-Aid announced they were pulling Zantac and generic ranitidine from their shelves.[107] Walmart also announced that it was pulling the drug from its shelves.[108]

83. Reading this complaint, one might ask: How did this happen? Why was this drug, which has been taken by millions, allowed to be sold? The answer is that the United States drug regulatory system is largely, if not entirely, reliant on the drug manufacturers themselves to perform adequate testing and report adverse events.

84. Defendants concealed the Zantac–NDMA link from consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like Zantac to the agency's attention.

85. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety:

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[105] Anna Edney, *Carcinogen Scare Sets Off Global Race to Contain Tainted Zantac*, BLOOMBERG (Sept. 18, 2019), https://www.bloomberg.com/news/articles/2019-09-18/sandoz-halts-distribution-of-zantac-after-carcinogen-concerns.

[106] *Dr Reddy tumbles on buzz of halting worldwide supply of Ranitidine*, BUSINESS STANDARD (Sept. 23, 2019), https://www.business-standard.com/article/news-cm/dr-reddy-tumbles-on-buzz-of-halting-worldwide-supply-of-ranitidine-119092300347_1.html.

[107] https://www.washingtonpost.com/health/2019/09/30/drugstores-are-pulling-zantac-like-heartburn-drugs-off-shelves-over-potential-cancer-risk/.

[108] https://www.cnn.com/2019/09/30/health/cvs-zantac-pulled-cancer-trnd/index.html.

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.[109]

86. The manufacturer's annual report also must contain "[c]opies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product."[110]

87. Defendants simply ignored these regulations and, disregarding the scientific evidence available to them, did not report to the FDA significant new information affecting the safety or labeling of Zantac. Further, the FDA simply doesn't have the resources to police and enforce this provision.

88. Defendants never provided the relevant studies to the FDA, nor did they present to the FDA with a proposed disclosure noting the link between ranitidine and NDMA.

V. TOLLING OF THE STATUTE OF LIMITATIONS AND ESTOPPEL

A. Discovery-Rule Tolling

89. Within the period of any applicable statutes of limitation, Plaintiffs could not have discovered through the exercise of reasonable diligence that high levels of the carcinogen NDMA was produced by Zantac ingestion.

[109] 21 C.F.R. § 314.81(b)(2).

[110] 21 C.F.R. § 314.81(b)(2)(v).

90. Plaintiffs did not discover, and did not know of, facts that would have caused a reasonable person to suspect that their injuries were caused by Defendants' concealment of the fact that high levels of the carcinogen NDMA were produced by Zantac. The information linking Zantac to NDMA was contained exclusively in articles that were published in scientific journals. Plaintiffs did not have access to these scientific articles because they were behind a paywall. And even had the articles been more widely available, the significance of these highly technical articles would not have been apparent to Plaintiffs.

91. Plaintiffs could not have reasonably discovered the true extent of Defendants' deception about Zantac's safety until Valisure filed its Citizen Petition disclosing the extremely high levels of NDMA produced by Zantac.

92. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

B. Fraudulent-Concealment Tolling

93. All applicable statutes of limitation have also been tolled by Defendants' fraudulent concealment throughout the period relevant to this action of Zantac's producing high levels of the carcinogen NDMA.

94. Instead of disclosing to consumers the link between Zantac and the carcinogen NDMA, Defendants continued to manufacture and sell Zantac without disclosing this information on the drug's label or elsewhere. Further, Defendants misled the public into believing Zantac was safe by repeatedly touting the safety of Zantac. Indeed, until the day it issued its recall, Defendant Sanofi still claimed that "longstanding science supports the safety of Zantac."[111]

[111] https://www.zantacotc.com/ (last visited Oct. 16, 2019).

C. Estoppel

95. Defendants were under a continuous duty to disclose to Plaintiffs the risk of NDMA exposure associated with Zantac.

96. Defendants knowingly, affirmatively, and actively concealed or recklessly disregarded the true risks of NDMA exposure associated with Zantac and never updated the drug's label to disclose this risk.

97. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

D. Continuing Tort

98. The continuing tort doctrine applies when there is a repeated or continuous injury and the tort is not completed until the last injury is inflicted or the wrongdoing ceases. In cases of continuing torts, the statutes of limitations do not begin to run until the date of the last tortious act.

99. The Plaintiffs used Zantac over extended periods. Each time a Plaintiff ingested Zantac, it constituted a continuing tort.

100. The time period associated with the Plaintiffs' statute of limitations did not begin to run until, at the earliest, the Plaintiffs' last use of Zantac.

VI. CLAIMS FOR RELIEF

COUNT I

PRODUCTS LIABILITY – DESIGN DEFECT

101. The Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

102. The Defendants manufactured, marketed, and sold Zantac during the periods set forth above.

103. Zantac is unreasonably dangerous and unsafe for its intended purpose because, when ingested, it forms extremely high levels of NDMA and other harmful metabolites in the body. NDMA is a human carcinogen associated with various types of cancers. Indeed, the chemical structure of ranitidine itself is inherently unstable, and contains the two chemical precursors to the formation of NDMA: a nitrite group and a dimethylamine (DMA) group.

104. The risks of NDMA formation in the human body from Zantac ingestion, and the concomitant risk of cancers associated with NDMA, were actually known to and foreseeable to all Defendants at all times during the period which they manufactured and sold Zantac. Even before Zantac was commercially launched in 1983 in the United States, as further described above, the scientific community expressed concern about the propensity of ranitidine to form NDMA in the body when ingested. Further, from the time of Zantac's launch until the present day, various scientific literature, as further described in this complaint, expressed concerns about NDMA formation from ranitidine. Plaintiff was unaware of this scientific literature, but Defendants were aware of it.

105. At the time Zantac left the Defendants' control, there was a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Zantac.

106. Zantac's design defect existed at the time Zantac left the Defendants' possession.

107. Zantac is not as safe as current technology could make it, nor is it as safe as then-current technology could make it. Indeed, there are several other classes of drugs that treat the

same condition, such as proton-pump inhibitors, which don't metabolize into NDMA when ingested.

108. The Defendants knowingly designed Zantac with the design defect that causes Zantac to form NDMA in the body when ingested, to maximize profits.

109. Zantac is not unavoidably unsafe and the harm was not caused by an unavoidably unsafe aspect of Zantac.

110. Zantac was approved by the FDA in 1983 pursuant to New Drug Application 0180703. Following the filing of NDA 0180703, there were numerous other NDAs filed by the Defendants, including, but not limited to, NDA Nos. 019090 (Glaxo Zantac injection), 019675 (Glaxo Zantac syrup), 020095 (Glaxo Zantac 150 capsule), 020251 (Glaxo Zantac effervescent 150), 021698 (Sanofi Zantac 150), 0200095 (Glaxo Zantac 300 tablet), 020520 (Sanofi Zantac 75 tablet), and 020745 (Sanofi Zantac 75 effervescent). In connection with each of these NDAs, the relevant Defendant that filed such NDA could have submitted an alternative or different formulation for Zantac, one in which Zantac wouldn't metabolize into NDMA and other harmful metabolites. But, no Defendant did so, instead, continuing to utilize the defective design of ranitidine, which caused the formation of NDMA and other harmful metabolites in the body upon ingestion.

111. Plaintiff ingested Zantac for an approved purpose and experienced cancers as a result of their Zantac use.

112. Had Plaintiff known of the defect in Zantac, she would not have taken Zantac. Instead, she would have taken a safer alternative to Zantac that wouldn't expose them to harmful levels of NDMA and other dangerous metabolites.

113. Plaintiff's cancer injuries were directly and proximately caused by Zantac while Plaintiff used Zantac in a reasonably foreseeable manner which recovery is sought.

COUNT II

PRODUCT LIABILITY – FAILURE TO WARN

114. The Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

115. The Defendants manufactured, marketed, and sold Zantac during the periods set forth above.

116. Zantac is not reasonably fit, suitable or safe for its intended purpose because the Defendants designed Zantac in a defective manner and failed to give adequate warnings or instructions at the time Zantac left the Defendants' control and after that.

117. The Defendants failed to provide any warnings of the dangers regarding the fact that NDMA and other harmful metabolites form in the body following ingestion of Zantac.

118. Plaintiff ingested Zantac for an approved purpose and experienced cancers as a result of their Zantac use.

119. Had Plaintiff known of the defect in Zantac, she would not have taken Zantac. Instead, she would have taken a safer alternative to Zantac that wouldn't expose them to harmful levels of NDMA and other dangerous metabolites.

120. Plaintiff's cancer injuries were directly and proximately caused by Zantac while Plaintiff used Zantac in a reasonably foreseeable manner which recovery is sought.

COUNT III

BATTERY

121. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

122. Since Glaxo invented ranitidine, and as fully set forth above, each Defendant knew that when ingested, Zantac metabolizes and forms high levels of NDMA in the body. During the period of time each Defendant sold Zantac, it knew Zantac formed excessive levels of NDMA in the body.

123. Decades before Zantac was first commercially sold in the United States in 1983, Glaxo knew that NDMA was carcinogenic. Each Defendant also knew at the time they sold Zantac that NDMA was a potent carcinogen.

124. At the time each Defendant manufactured and sold Zantac, it manufactured and sold Zantac for the express purpose of being used by unwitting consumers, who didn't know that when ingested, Zantac formed excessive levels of NDMA in the body. Therefore, at all relevant times, the Defendants knew that was certain or substantially certain that the Plaintiff would be subjected to excessive levels of NDMA upon ingestion of Zantac, which they manufactured and sold.

125. Plaintiff ingested Zantac, and, as a result, was exposed to excessive amounts of a potent carcinogen — NDMA. The Plaintiff's exposure to NDMA was caused directly by Defendants.

126. No reasonable person would want to be subjected to excessive levels of a potent carcinogen, and thus, the Plaintiffs' exposure to NDMA constituted an offensive contact caused by Defendants.

127. Although Plaintiff voluntarily ingested Zantac, at no time did Plaintiff know that Zantac ingestion resulted in the formation of excessive levels of NDMA in the body. If Plaintiff had known this, she would not have taken Zantac. Therefore, Plaintiff never consented, implicitly or explicitly, to ingesting a substance that would cause large amounts of NDMA to be formed in her body.

128. The Defendants' battery upon the Plaintiff proximately caused her injuries and damages for which recovery is sought.

COUNT IV

FRAUD BY OMISSION

129. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

130. At all times, the Defendants had a duty to exercise ordinary care in the design, manufacture, marketing, and sale of its pharmaceutical products, including Zantac.

131. The Defendants have a duty to refrain from selling unreasonably dangerous products, including the duty to ensure that their pharmaceutical products do not cause patients to suffer from foreseeable risks of harm.

132. The Defendants had a duty to monitor the adverse effects associated with pharmaceutical products, including Zantac.

133. The Defendants have a duty to exercise reasonable care when they undertake affirmative acts for the protection of others.

134. The Defendants owe these duties to Plaintiff because it was foreseeable to Defendants that patients like Plaintiff would ingest and consequently be endangered by Zantac.

135. The Defendants also owed a duty to speak because they were in possession of information about Zantac that was not readily available to Plaintiff and Plaintiff's physicians, made misrepresentations about the safety of Zantac to Plaintiff and Plaintiff's physicians while suppressing material facts, and actively concealed material information about Zantac from Plaintiff and Plaintiff's physicians, including that when ingested, Zantac formed high levels of NDMA and other dangerous and carcinogenic metabolites in the human body.

136. The Defendants knew that this information was not readily available to Plaintiff and her doctors, and Plaintiff and her doctors did not have an equal opportunity to discover the truth. Plaintiff and her doctors had no practicable way of discovering the true state and timing of the Defendants' knowledge.

137. The Defendants intentionally omitted from their prescriber and patient labeling any type of warning alerting patients and their physicians that when ingested, Zantac forms high levels of NDMA and other harmful metabolites in the body. And, given that Defendants advertised and promoted Zantac as being safe, the Defendants had a duty to speak and reveal the fact that they knew when ingested, Zantac formed NDMA and other harmful metabolites in the body.

138. Plaintiff and her doctors justifiably relied on the Defendants' product labeling and other representations.

139. Had the Defendants not omitted this information about the safe use of their drugs from the prescriber and patient labeling, doctors would not have prescribed (or recommended), and patients would not have insisted upon or taken Zantac. But for the Defendants' omissions, Plaintiffs would not have consumed Zantac.

140. If Plaintiff had been properly warned about the dangers of Zantac use, she would not have taken Zantac, and would not have developed her injuries, or been at risk for developing cancer from Zantac usage.

141. Plaintiff and her doctors justifiably relied on the Defendants' omissions regarding Zantac.

142. Had the Defendants disclosed that they were aware of, but intentionally withheld, that Zantac forms NDMA and other harmful metabolites in the body once ingested, Plaintiff would not have ingested Zantac.

143. Plaintiff was injured as a direct and proximate result of Defendants' material omissions.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court enter an order or judgment against Defendants, including the following:

A. Actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

B. Exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;

C. Costs, including reasonable attorneys' fees, court costs, and other litigation expenses; and

D. Such other and further relief as the Court deems just and proper.

VIII. JURY DEMAND

Plaintiff hereby demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: January 2, 2020

Respectfully submitted,

By: /s/ James E. Cecchi

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